

**SUMMARY OF THE
FIFTH INTERIM MEETING OF THE
NATIONAL ENVIRONMENTAL LABORATORY ACCREDITATION CONFERENCE
DECEMBER 14-17, 1999**

INTRODUCTION

The National Environmental Laboratory Accreditation Conference (NELAC) held its Fifth Interim Meeting, NELAC Vi, December 14-17, 1999, at the J.W. Marriot Hotel in Washington, DC. The meeting was sponsored by the U.S. Environmental Protection Agency (USEPA). There were 265 individuals registered for the meeting.

OPENING PLENARY SESSION

Ms. Jeanne Mourrain, NELAC Director, welcomed participants to the opening plenary session and introduced the NELAC Board of Directors: Dr. James Pearson (Chair), Dr. Kenneth Jackson (Past Chair), Dr. Charles Brokopp (Chair-Elect), Ms. Lisa Doucet (Executive Secretary), Dr. Paul Kimsey, Ms. Sylvia Labie, and Ms. Jackie Sample. Dr. Ronald Cada, Ms. Barbara Finazzo and Ms. Anne Rhyne were unable to participate in this meeting. She then introduced the committee chairs and reviewed the conference schedule. Ms. Mourrain thanked members of the Board and committee chairs for their efforts.

Ms. Mourrain remarked that she had recently attended a presentation on diversity and noticed that it shared much with NELAC — participation of federal and state agencies, government and private sector parties. She commented that this diversity has helped NELAC to incorporate many different perspectives to improve the standards and to develop the best possible solution for a national program.

Ms. Mourrain then introduced Dr. James Pearson, NELAC Chair, from the Virginia Division of Consolidated Laboratory Services. She said that Dr. Pearson is a man holding many responsibilities, and NELAC is fortunate to have him as chair this year.

Remarks from the Chair

Dr. Pearson thanked the Board of Directors, committee members, and participants for their efforts in NELAC. He said that NELAC is entering a new phase with the National Environmental Laboratory Accreditation Program (NELAP), which is implementation, and will now be dealing with “real,” not hypothetical, issues. He encouraged everyone to participate in the committee sessions and pointed out that there is a “NELAC Needs You” form in the attendee packets. He also encouraged new attendees to talk with the Board members about the background of NELAC.

Dr. Pearson reviewed some of the highlights for this meeting. He said that the accredited laboratories will be announced in June, 2000 and there may be as many as 1,300 laboratories. He mentioned that a new regulation has been promulgated by USEPA's Office of Water which requires that proficiency tests for drinking water be method specific. January 3, 2000, has been set as the effective date for the new rule, but there is some question about the implementation date. Because the NELAC Standards differ from the USEPA regulations, Dr. Pearson asked participants to share ideas at the Proficiency Testing Committee session so that a solution can be found.

Before closing, Dr. Pearson asked participants to pay attention to the ground rules which would be posted in each session. He then introduced the key note speaker, Mr. Henry L. Longest II, Deputy Assistant Administrator of USEPA's Office of Research and Development.

Keynote Address

Mr. Longest congratulated NELAC on their accomplishments in developing standards that are now being implemented. Eleven states have been approved as NELAP accrediting authorities and the laboratories will be accredited starting in June, 2000. He remarked that we are now seeing NELAC's "fruit of labor." He commended the NELAC Director, the first Accrediting Authorities, the USEPA Regions, the States, and the Environmental Laboratory Advisory Board (ELAB) for their team effort.

Mr. Longest reviewed some of the changes taking place within the USEPA. He said that a new Office of Environmental Information has been formed to improve information management and ensure the quality of data. He said that there are three principal offices and the Quality Information Council, which incorporated to a large degree the Environmental Monitoring Management Council (EMMC). NELAC and implementation of Performance Based Measurement Systems (PBMS) will remain with the Office of Research and Development (ORD). Mr. Longest said that this restructuring within USEPA should not have a great impact on NELAC, other than its organizational location. NELAC will stay with ORD under the National Environmental Research Laboratory in Research Triangle Park, NC. Since Ms. Betsy Dutrow, having returned to the Office of Air and Radiation, no longer is assigned responsibilities with NELAC and the Environmental Laboratory Advisory Board (ELAB), Mr. David Friedman will serve as the acting Designated Federal Officer for ELAB. He noted that training for the affected stakeholders (e.g., permit writers) is currently a major issue for implementation of PBMS and much remains to be done.

Mr. Longest then listed goals for NELAC which he feels are necessary to ensure its continued success:

- a consistent, strong assessment program,
- good assessors to ensure the quality of data,
- incorporate additional states into the system,

- incorporate PBMS;
- continue efforts to complete transition; and
- help the laboratories respond to NELAC.

Mr. Longest said that EPA will be withdrawing support from NELAC and that EPA had always considered that NELAC should be a self-sustaining program, funded by its stakeholders. He recommended that NELAC be moved into the private sector and said that EPA never intended for NELAC to become a USEPA program. Mr. Longest also said that USEPA anticipated a continued partnering role within NELAC, but that ORD needs to concentrate on its research priorities.

Update from the Accrediting Authorities

Dr. Pearson introduced Mr. Richard Sheibley and Dr. Carl Kircher to provide an update from the NELAP Accrediting Authorities. Mr. Sheibley presented the following summary:

At NELAC V, the 11 newly recognized NELAP Accrediting Authorities met for lunch and to discuss the process of implementing the NELAP accreditation. At that meeting, we agreed to meet via teleconference to identify, discuss and attempt to resolve any issues that arose as we attempted to implement the NELAC standards. Our first teleconference occurred approximately 2 weeks after conclusion of NELAC V in Saratoga Springs. We quickly recognized that these meetings were essential to keep the lines of communication open, therefore, we agreed to meet every 2 weeks.

Because the entire process of Accreditation to the NELAC standards was new, our discussions have been lively and thought provoking. As individuals charged with the responsibilities of accrediting laboratories using these standards for the first time, the "how to do" questions needed to be answered. Our goal as a group was and is to have a uniform interpretation of the standards, which will insure that all of the laboratories receiving NELAP Accreditation have been held to the same standards. No small undertaking.

Early in our discussions, we recognized that the EPA Regional Assessors – the individuals charged with the review of the current and any future Accrediting Authorities – needed to be kept abreast of our discussions. We extended an invitation to a representative from the EPA regions to join in our discussions.

One of the first issues that everyone noticed was the difference in the way we had approached Fields of Testing. To provide a mechanism for comparison of these differences, we worked on single document that listed the Fields of Testing offered by the individual states. The list provides a summary of the Fields of Testing available from each state and is posted on the NELAC website. From this list, laboratories will be able to clearly see what accreditation is offered by the individual states. As you can imagine, this document required an incredible amount of work and I would like to thank Dr. Carl Kircher of Florida who compiled the original list and coordinated the numerous revisions.

As an outgrowth of these discussions on Fields of Testing, we explored the possibility of recommending a minimum list of Fields of Testing for the Accrediting Authorities. We

discussed advantages and disadvantages of required minimum sets of Fields of Testing. A minimum list might discourage other states from becoming NELAP Accrediting Authorities. As a group, we decided that at this time, we would not make this recommendation. Instead, we are continuing to cooperate to insure that any differences among the AAs do not interfere with the implementation of NELAP accreditation and to insure a smooth transition period for both the laboratories and for the Accrediting Authorities.

The Fields of Testing as they relate to PT Studies was also discussed. Our group has been in contact with the Chapter 2 PT committee and hope that a resolution of this issue will be forthcoming from that committee. At issue is that Chapter 2 defines Field of Testing as Program – Matrix- Analyte and Accreditation is by Program – Method – Analyte.

This group discussed recommendations concerning the effective date for the first Proficiency Test Samples that would or could be counted toward NELAP accreditation. A suggestion had been made to include PT studies beginning January 1, 1999. After carefully reviewing and discussing the language contained in both the 1999 NELAC standards and the 1998 NELAC standards we found no provisions that would allow this option. We concluded that, according to the NELAC standards, only PT samples received and analyzed after July 1, 1999 would be acceptable for determining NELAP accreditation.

Recently, the US EPA proposed a regulatory change for the drinking water program that mandates that a PT sample be performed annually by each method for which the laboratory is seeking to obtain or to maintain accreditation. Although this requirement may not be in direct conflict with the NELAC requirements, the implementation and tracking of this requirement will certainly provide a challenge to the laboratories and to the Accrediting Authorities. Since this is a recent development, we and I'm sure others, are considering any possible conflicts and exploring possible solutions.

Individually and collectively, we reviewed and commented on the proposed Checklists that will be one of the cornerstones of the Accreditation process. We believe that the completed checklist reflects all of the elements contained in Chapter 5. The on-site assessment committee posted a Chapter 5 checklist based upon the 1999 standards on the NELAC website.

We support the efforts to provide assessor training as soon as possible. We are hopeful that a proposed training session occurs in late March or early April.

The time frame and the details on how and when laboratories could obtain Secondary Accreditation were discussed. Although this will not be an issue until the Primary Accrediting Authorities grant accreditation, we have agreed to work together to process these applications for secondary accreditation as quickly as possible. With cooperation among the Accrediting Authorities, Secondary Accreditation can be granted within 30 days of a laboratory applying to an Accrediting Authority.

The NELAP recognized Accrediting Authorities are committed to continuing to work together in a cooperative and constructive fashion to insure that NELAP Accreditation of the first class of laboratories occurs in a timely manner. Currently, we are on track to meet that goal.

Mr. Sheibley and Dr. Kircher then entertained questions from the audience.

Closing Comments

Dr. Pearson provided some closing comments for the opening plenary. He asked participants to review the materials provided to them and to participate in the NELAC process. He also reminded everyone that there was a mixer in the evening from 5 to 7 p.m.

COMMITTEE WORKING SESSIONS

Following the opening plenary session, concurrent working sessions were held for all 13 standing, administrative, and *ad hoc* committees, and the Accrediting Authority Review Board. Progress made by each committee, as well as principal unresolved issues (and expected time frames for addressing them) were presented in the closing plenary session. In keeping with the goals established for the national NELAC meetings, all working sessions were of an open-forum format in which attendees were encouraged to participate.

Field Measurements—Chair: Dr. Bart Simmons

Some of the highlights and substantive issues for the Field Measurements Committee were the recent adoption of the International Standards Organization (ISO) 17025 standard, priorities for field measurement standards, and measurement of source emissions (MSE). The timing for incorporating ISO 17025 into the NELAC standards is uncertain. Dr. Simmons said that discussions on this topic have been more focused than in the past and although it represents a small amount of data, it is valuable and may be used as a guideline for other efforts. Other unresolved issues include qualification of individuals, accreditation for field testing at a temporary location, and liability for on-site assessors.

By February, 2000, the committee plans to complete its transition to becoming a standing committee. One of their first tasks will be to select a committee chair. They also plan to nominate a subcommittee on sampling standards and one on measurement of source emissions (by January, 2000). The committee intends to revise the proposed MSE standards by March, 2000.

Accrediting Authority Review Board—Chair: Mr. George Mills (Ms. Judy Duncan, Acting Chair)

Some issues for the Accrediting Authority Review Board (AARB) include the scope of AARB duties, the AARB process for review of appeals, and the review of NELAP. The AARB feels that any additional duties may be beyond their abilities. With respect to the appeals process, it was noted that the AARB is a fact-finding, recommendation body and Ms. Duncan recognized the need for the AARB to act expeditiously. The AARB's review of NELAP is not yet complete. They are currently in the process of reviewing the ISO guidelines. The AARB hopes to complete their review of NELAP by the end of March, 2000, so that they can report to NELAC in June, 2000. There were also questions about membership appointments to the AARB and the AARB intends to make a recommendation that a minimum number of members on the AARB be from NELAP states.

Program Policy and Structure—Chair: Dr. Marcia Davies

One substantive issue for the Program Policy and Structure Committee is Section 1.6.3 regarding the AARB. The committee has proposed changes to the section and requests comments by January 15, 2000. The committee intends to meet jointly with the Accrediting Authority Committee and the NELAC Director to discuss this issue further. Another issue is the scope of accreditation. The committee will re-examine Section 1.8 and Figure 1-3 for consistency with the way that NELAC is proceeding. There will also be some additions and minor revisions to the NELAC glossary (refer to committee minutes for a list of changes). The committee will be adding language to Section 1.5.3, regarding Federal Accrediting Authorities (FAAs) as secondary accreditors. The sense is that the FAAs will exist to accredit only federal laboratories and they will not act as secondary AAs for the states. The committee will revisit Section 1.6.1 on Board responsibilities in policy making. An unresolved issue is the participation of the Indian Tribes in NELAC. This issue has been assigned to USEPA Regions (Indian Nation Coordinators) for information gathering (e.g., numbers of laboratories and interest in NELAP).

The committee plans to work in an ongoing fashion with other committees on scope of accreditation issues. The committee will also consider incorporating the current NELAC policies into Chapter 1, if suitable.

Proficiency Testing—Chair: Ms. Barbara Burmeister

Highlights of the Proficiency Testing Committee included the development of a guidance document for the Section 2.0 interim standards, development of a list of PT fields of testing with acceptance criteria, and streamlining of Appendix H for air (which will be proposed for vote at NELAC VI). It was unresolved whether the Transition Committee or NELAP AA workgroup will endorse the use of the PT fields of testing list for all laboratories seeking NELAP accreditation. It is also unknown when the NELAP AA workgroup will require laboratories to analyze PT samples for analytes beyond the Water Supply (WS) and Water Pollution (WP) scope. The committee hopes to resolve both these questions as soon as possible.

The committee plans to finalize the Section 2.0 guidance document and the list of PT fields of testing and acceptance criteria by February 1, 2000 and requested comments on either of these by January 15, 2000. Once complete, they will be posted on the NELAC Website.

By May 1, 2000, the committee plans to have completed the following:

- finalize changes to Appendix F on environmental toxicology and propose for vote at NELAC VI,
- finalize Appendix G on radiochemistry after USEPA National Standards for Radiochemistry are published (Appendix G will be proposed for vote at NELAC VI),
- clarify language in Section 2.4.1 regarding PT samples,
- revisit the definition of matrix as it pertains to PT fields of testing,

- and re-evaluate the standards per recent changes in the Safe Drinking Water Act regulations.

The committee will update the list of Frequently Asked Questions for proficiency testing and submit their responses to the Board of Directors for review as soon as possible.

On-Site Assessment—Chair: Mr. Steven Baker (R. Wayne Davis, Acting Chair)

Highlights for the On-site Assessment Committee included the quality systems checklist, which is ready to use, and the basic training course for assessors, which is nearing completion, and the pilot course, which is planned for early next year. Some of the unresolved issues for the committee included:

- technical checklists (mandatory methods, quality control, and PBMS),
- confidential business information (CBI) as it relates to third-party assessors,
- standard operating procedures review by assessors (all or percentage),
- what constitutes a “passing” test grade for the basic training course,
- technical training courses (content and depth),
- “approval” of trainers and training courses,
- and “refresher” training courses.

The committee has noted that some of the written comments have been misplaced and asked that comments be resubmitted to the committee if a response has not been received. Future plans are to update Chapter 3 to the 1999 NELAC Standards, address comments from the Field Measurements *ad hoc* Committee, and possibly develop technical training courses.

Accreditation Process—Chair: Dr. John Griggs

The Accreditation Process Committee plans to review existing language on mobile laboratories and develop new language by March 15, 2000, for mobile laboratories which are associated with fixed-based laboratories. They will also review language in the “change of ownership” section by March 15, 2000, and consider deleting some parts that have to do with assuming liability. The committee plans to coordinate with the Field Activities Committee on mobile laboratories and field measurements regarding definitions and update language in the standard to reflect changes in other chapters.

Quality Systems—Chair: Mr. Joe Slayton

Highlights for the Quality Systems Committee focused on Appendix D. This included Section D.2 on toxicity testing (major re-write to expand the scope), Section D.3 on microbiology testing (Safe Drinking Water Act requirements with a practical approach for the National Pollutant Discharge Elimination System), Section D.4 on radiochemical testing (“should” vs. “shall”), and a

new Section D.5 on air testing (“lab quality control [QC]” vs. “field QC”). Other substantive issues for the committee included “sample tracking” vs. “chain of custody” records in Section 5.12 and removal of “shoulds,” etc., from the checklists so that they are “auditable.” Some unresolved issues include laboratory activities/responsibilities vs. field activities/responsibilities, matrix spike/matrix spike duplicate (topic has re-arisen due to recent proposals in Superfund), QC “substitutions” (e.g., matrix spike or surrogates for the laboratory control sample), and categories of chain of custody records. The committee plans to have these issues resolved by NELAC VI. It was requested that commentors submit proposed language in written electronic form. (See NELAC website www.epa.gov/ttn/nelac for standard format.)

Future plans of the committee are to:

- finalize updates to Sections D.2 to D.5,
- work with the Field Activities Committee on the scope of Chapter 5 (where to draw the line between laboratory and field),
- revisit the glossary to assure consistency with Quality Systems (e.g., detection limit, laboratory control sample),
- convene a subcommittee on radiochemical testing,
- clarify “chain of custody” (e.g., “sample transmittal” and “internal”),
- and clarify/reorganize Section 5.9 on measurement traceability and calibration.

The committee plans to take action on these items by NELAC VI.

Accrediting Authority—Chair: Mr. John Anderson

One issue for the Accrediting Authority Committee was the July 1, 2000, sunset clause on two-year extensions for initial accrediting authority applicants to comply with the NELAC Standards. The committee is considering removing this clause. Questions were also posed regarding enforcement-sensitive documents during on-site assessments of accrediting authorities. It was noted that the committee does not want to jeopardize any legal processes.

The committee plans to propose changes to Section 1.6.3 about the Accrediting Authority Review Board by April 1, 2000. These changes pertain to non-voting members, representation of federal non-USEPA accrediting authorities, and accreditation concerns raised by proposed Section 1.5.3.1 regarding federal agencies accrediting private sector laboratories. Some of the provisions from the latest revision of Section 1.6.3 were inadvertently omitted from the last published proposed changes; these will be added back in.

Future plans for the committee are to hold a joint teleconference with the Program Policy and Structure Committee regarding the AARB by February 29, 2000, and complete teleconferences to discuss additional comments received at NELAC Vi by May 1, 2000.

Membership and Outreach—Chair: Dr. Irene Ronning (Mr. Mike Ciolek and Ms. Marge Prevost, Acting Chairs)

Highlights for the Membership and Outreach Committee included suggestions for improvement of the NELAC Website, posting updated fact sheets on the website, and Frequently Asked Questions (FAQs) from two committees which will be reviewed and added to the website. The committee is considering various outreach vehicles to potential accrediting authorities and requests that any ideas be sent to Dr. Irene Ronning. An unresolved issue is Article 2, Section 2 of the by-laws, which is currently reserved. The committee is investigating what was removed from this section (possibly the identification of NELAC voting members) and may eliminate Article 2 if it is no longer necessary. Future plans include identifying a designated liaison from each standing committee (by February 1, 2000), contacting PT providers to send fact sheets with PT samples, and establishing more links on the NELAC Website to related associations.

Nominating Committee—Chair: Dr. Kenneth Jackson

Dr. Jackson said that the formal slate of nominees for the NELAC Board of Directors will be presented prior to NELAC VI. Criteria for selection of Board members include: geographical representation, government affiliation, institutional knowledge of NELAC, and a track record of being an active participant. He announced that the Board will present Ms. Sylvia Labie as the nominee for Chair-Elect. Mr. Joe Slayton and Ms. Ann Marie Allen will be nominated as replacements for Ms. Barbara Finazzo and Dr. Ronald Cada. Biographical information for each of the nominees will be presented on the NELAC Website.

Regulatory Coordination—Chair: Dr. Michael Miller

A substantive issue for the Regulatory Coordination Committee is fields of testing, which will require cross-chapter coordination. Their discussions related to the current status of the eleven accrediting authorities and proposed restructuring of fields of testing. The committee discussed the impact of USEPA's mandatory quality system on NELAC laboratories and states and reviewed USEPA's recent changes to the Safe Drinking Water Act (i.e., the unregulated contaminants monitoring rule from September, 1999, and changes to CFR 141 and 143 from December, 1999). Unresolved issues include the scope of accreditation proposal (ongoing) and a review of USEPA's October 1999 regulatory agenda (by July, 2000). The committee also plans to collect recent state regulations and legislation for implementation of NELAC. They will prepare a request letter (by March, 2000) and evaluate available materials (by July, 2000).

Future plans for the committee include: formulation of a recommendation to the NELAC Board of Directors that USEPA and the NELAC Quality Systems Committee evaluate the impact of USEPA's mandatory quality system on NELAC laboratories and states (by April, 2000); review of sample laboratory application currently posted on NELAC Website (by May, 2000); and consideration of the development of model generic standard operating procedures (SOPs) and Quality Manuals for small laboratories (ongoing).

National Database—Chair: Mr. Matt Caruso

The National Database Committee reviewed the following with USEPA's database contractor: types of data to be stored, mechanism for AAs to upload data, process for notifying secondary AAs of actions taken by the primary AAs, and overall capabilities of the database (e.g., kinds of reports that can be generated). The committee plans to determine by January 31, 2000, what types of "canned" questions the database should be able to answer. Mr. Caruso said that generic question(s) may be sent to him by email (at "caruso@wadsworth.org") until January 15, 2000. He asked that commentators characterize their role in asking the question (e.g., accrediting authority, client, regulator). The committee plans to continue to work with USEPA and its contractor in bringing the database on-line by July, 2000.

Transition—Co-chairs: Dr. Charles Brokopp and Ms. Carol Batterton

Some of the issues that the Transition Committee is working with are: increased communication with the Accrediting Authority workgroup (post notes on NELAC Website), assessor training, recognition of additional AAs, and committee composition and tasks. The committee wants to have the same level of training available for all assessors, and hopes to have assessor training in early 2000. The committee plans to nominate new members by December 31, 1999. They also hope to resolve questions about interim accreditation and the timing of accreditation by January 31, 2000. Because the continued role, support, and involvement of EPA is in question, the committee intends to support the Board of Directors as they develop a strategy and options for future support of NELAC by May 30, 2000. It was noted that USEPA funding is in place for NELAC through the year 2001.

CLOSING PLENARY SESSION

In his closing comments, Dr. Pearson said that NELAC needs more people to be involved in its activities. He said that the conference needs strong, active, engaged members and asked participants to complete the nomination forms. He also noted that any comments for the On-site Assessments Committee should be sent to Mr. Wayne Davis. Dr. Pearson asked participants to submit comments in writing and to utilize the comment form posted on the NELAC Website. With respect to comment responses, he suggested that people contact the Board liaisons for the appropriate committee if their comments do not receive a timely response.

Dr. Pearson brought up the issue of communication between committees. He asked that committee members read through each others standards and to let the committee chairs know if there are inconsistencies. Finally, he asked everyone to attend the NELAC VI meeting in June, 2000. He suggested that participants get early reservations and mentioned that there are secondary hotels lined up.

Ms. Jeanne Mourrain, NELAC Director, provided some closing comments. She thanked several people for their efforts including: Dr. Margo Hunt (assessor training), Mr. Jeff Worthington (national database), Ms. Betsy Dutrow (initial planning of NELAC VI), Dr. Fred Siegleman and

Ms. Lisa Doucet (final plans for NELAC Vi), Research Triangle Institute (logistical support), Ms. Betty Maisoneuve (contract management), Ms. Nancy Wentworth (continuing support), Mr. Jerry Parr and Ms. Marlene Moore (information on applicant labs and pilot program for assessor training).

After hearing comments during the various sessions, Ms. Mourrain reminded the NELAC community that accreditation does not prevent fraud. Accreditation is an assessment of capability, not a safeguard against fraud. Second, she noted that assessors are not necessarily advisors. Although many assessors do provide advice, it is not a requirement under. Third, she reminded everyone that the goal is uniform standards. Although NELAC should keep its sights on perfection, it is critical to move forward now, keeping in mind that modification of the standards is always possible.

Ms. Mourrain noted that the deadline for comments to committees is March 1, 2000. She also reminded participants of the ELAB Open Forum on December 16, 1999, from 5 to 6 p.m. and the ELAB Meeting on December 17, 1999, from 8 a.m. to 12 p.m.